REMARKS

The present invention relates to novel methods for inducing an anti-tumor response in a mammal.

Claims 23-26, 29-37, 43-50, and 55-56 are currently pending. Claims 1-20 were canceled in previous Amendments, claims 21, 22, 27, 28, 38-42, and 51-54 are canceled herein, and claims 23-26, 29-37, 43, 45-47, 55, and 56 are amended herein. No new matter is added by way of this Amendment.

Due to the amount of time that has lapsed between the previous Office Action and the present Office Action, and due to the recent transfer of this application to the Applicant's new patent counsel, the Applicant provides herewith as Appendix A to this Response a listing of the claims that the Applicant believes were pending immediately prior to filing this Response for the Examiner's convenience.

Rejections

(1) Claims 21-56 stand rejected by the Examiner under 35 U.S.C. §112, second paragraph, for various reasons (A)-(O).

(2) Claims 21 and 23-56 stand rejected by the Examiner under 35 U.S.C. §112, first paragraph, for failing to satisfy the written description requirement.

(3) Claims 21-56 stand rejected by the Examiner under 35 U.S.C. §112, first paragraph, for failing to satisfy the enablement requirement, for various reasons (A)-(E).

(4) Claims 21, 22, 24, 32, 33, 35, 38, 40, 41, 51, 52, and 54 stand rejected by the Examiner under 35 U.S.C. §102(b) as being anticipated by Berd, et al. (Cancer Research, 1986 46:2572-2577).

(5) Claims 21-24 stand provisionally rejected by the Examiner under 35 U.S.C. §101 as claiming the same invention as that of claims 21-24 of co-pending application No. 11/015,769.

Responses

In response to rejection (1), while not necessarily agreeing with the Examiner's statements, the Applicant has amended the claims as shown above, solely to expedite prosecution of this application. With regard to rejection (1)(O), the Applicant respectfully traverses the rejection. The Applicant asserts that the term "about" as used in the present claims is not vague and indefinite. The term "about" has been found by a court of law to be definite, and is

interpreted with its ordinary dictionary meaning of "approximately" (see Merck v. Teva Pharmaceuticals, Docket No. 04-1005, page 9, line 3; copy enclosed). The Applicant respectfully requests that the Examiner take interpret "about" to mean "approximately."

In view of the foregoing arguments and amendments, the Applicant respectfully submits that all of the various reasons for rejection have been overcome, and requests that this rejection be withdrawn.

With regard to rejection (2), the Examiner states that there is no support in the specification for the genus of "immunomodulator agents." In response to rejection (2), the Applicant points out that claim 23 does not claim a genus of immunomodulator agents. Rather claim 23 is directed specifically to cyclophosphamide, and the Applicant asserts that use of cyclophosphamide is adequately described in the present specification such that the Applicant has demonstrated possession of the claimed invention as required by 35 U.S.C. §112, first paragraph. With regard to claims 21, 27, 28, 38-42, and 51-54, these claims have been canceled herein, and this rejection is rendered moot in view of the cancellation of these claims. The Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

With regard to rejection (3), the Examiner states that claims 21-56 are not enabled by the present specification. As this rejection pertains to claims 21, 22, 27, 28, 38-42, and 51-54, the Applicant asserts that this rejection is rendered moot in view of the cancellation of these claims. With respect to remaining claims 23-26, 29-37, 43-50, and 55-56, the Applicant presents the following arguments for the Examiner's consideration.

Regarding rejection (3)(A), the Examiner states that the claims do not require a resulting therapeutic effect when the claimed methods are performed. The Examiner states that the claims do not require that the patient experience therapeutic regression of a tumor or prevention of tumor progression. While not necessarily agreeing with the Examiner's assertions, the Applicant has amended claims 23, 46, and 55 herein to recite that the method requires a therapeutic regression of a tumor or prevention of a tumor progression. Therefore, the Applicant asserts that this rejection is rendered moot in view of this amendment.

Regarding rejection (3)(B), the Examiner states that claims 46-50 do not require cyclophosphamide. The Applicant points out that this rejection is rendered moot in view of the amendment to claim 46 to include administration of cyclophosphamide.

Regarding rejection (3)(C), the Examiner states that claims 21-32, 34-47, 49-51, and 53-56 encompass methods of inducing anti-tumor responses in patients having metastatic disease to various organs. The Examiner states that post-filing art suggests that treatment of metastatic disease is unpredictable, with the exception of treatment of melanoma metastatic to the lung. With regard to claims 21, 27, 28, 38-42, 51, and 53, these claims have been canceled herein, and this rejection is rendered moot in view of the cancellation of these claims. Regarding claims 23-26, 29-32, 34-37, 43-47, 49, 50, and 55-56, the Applicant respectfully traverses this rejection.

The Applicant asserts that treatment of metastatic disease is not unpredictable because the treatment method of the present invention is immunotherapy. Immunotherapy illicits an immune response wherever an immune response is needed. By its very nature, the vaccine of the present invention, when administered in accordance with the immunotherapy regimen described in the present specification, will be present throughout the body and will attack a tumor at any point in the body, whether or not it is metastatic. Therefore, the fact that a tumor has metastasized to another part of the body does not have an effect on the efficacy of the vaccine on the metastases. The Applicant has demonstrated, as cited by the Examiner, that the presently claimed methods were used to treat a metastasized lung melanoma tumors. The Applicant has also had success in treating metastasized ovarian and renal cancers. For these reasons, the Applicant respectfully requests reconsideration and withdrawal of this rejection.

Regarding rejection (3)(D), the Examiner states that claims 21-28 and 30-56 encompass haptenized tumor cells where the hapten is not DNP. With regard to claims 21, 27, 28, 38-42, and 51-54, these claims have been canceled herein, and this rejection is rendered moot in view of the cancellation of these claims. The Examiner states that only haptenization with DNP is taught in the current specification, and that it would require undue experimentation to determine how to haptenize tumor cells with other claimed haptens. The Applicant respectfully traverses this rejection.

The Applicant asserts that the processes for haptenization of cells with haptens, such as DNP or TNP, for example, are already known in the art, and need not be taught in the present specification. The Applicant concedes that some routine experimentation by a person of skill in the art may be necessary to determine the exact procedure for haptenizing tumor cells with a specific hapten, but this experimentation would not be undue. In addition, the Applicant points out that the specification recites several papers that discuss the several different haptens claimed

in the present invention (see published application, paragraph [0069]). Additional references include: (1) Kim BS, Jang YS. Constraints in antigen processing result in unresponsiveness to a T cell epitope of hen egg lysozyme in C57BL/6 mice. Eur J Immunol 1992;22:775-82; (2) Nahas F, Leskowitz S. The ability of hapten-conjugated cells to induce cell-mediated cytotoxicity is affected by the mode of hapten linkage. Cell Immunol 1980;54(1):241-7.; and (3) Sherman LA, Burakoff SJ, Benaceraff B. The induction of cytolytic T lymphocytes with specificity for p-azophenylarsonate coupled syngeneic cells. J Immunol 1978;121:1432-6. The Applicant asserts that it is well-known in the art how to haptenize cells with various types of haptens, and that one of skill in the art would not be under any undue burden to determine the proper process for haptenizing tumor cells with various haptens. The Applicant respectfully requests reconsideration and withdrawal of this rejection.

Regarding rejection (3)(E), the Examiner states that claims 21-40, 42, 43, and 45-56 encompass treatment of a mammalian patient that is not a human. The Examiner states that there would be undue experimentation required to practice the present invention with livestock or domestic pets. With regard to claims 21, 22, 27, 28, 38-40, 42, and 51-54, these claims have been canceled herein, and this rejection is rendered moot in view of the cancellation of these claims. Regarding claims 23-26, 29-37, 41, 43, 45, 55, and 56, the Applicant, solely for the purposes of expediting prosecution, has amended the claims to recite treatment of a human patient. Therefore, this rejection is rendered moot in view of the amendments to the claims.

In view of the foregoing arguments with respect to rejection (3), the Applicant requests that the Examiner reconsider and withdraw the rejection.

In response to rejection (4), the Applicant notes that this rejection is rendered moot with respect to certain claims 21, 22, 38-41, 51, 52, and 54, in view of the cancellation of these claims. With respect to claims 24, 32, 33, and 35, the Applicant notes that all of these claims, as amended, depend from claim 23, which has not been rejected by the Examiner. Therefore, the Applicant requests the Examiner to reconsider and withdraw this rejection with respect to claims 24 32, 33, and 35.

In response to rejection (5), the Applicant acknowledges the Examiner's provisional double-patenting rejection. The Applicant notes that U.S. Application No. 11/015,769 is a continuation of the present application, and has not yet been examined. The Applicant agrees to

address this provisional double-patenting rejection should it become an issue prior to grant of the presently rejected claims.

Summary

The Applicant respectfully submits that each rejection of the Examiner to the claims of the present application has been either overcome or is now inapplicable, and that each of claims 23-26, 29-37, 43-50 and 55-56 is in condition for allowance. Reconsideration and allowance of each of these claims are respectfully requested at the earliest possible date.

Respectfully submitted,
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Enclosures: Petition for Three-Month Extension of Time
Appendix A: Copy of Claims Pending Prior to Office Action Response
Appendix B: Clean Copy of Amended Claims
Merck & Co. v. Teva Pharmaceuticals, Inc.